FEB - 5 2014

510(k) Summary

K132613

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: August 8, 2013

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
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2. General Information

2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction Device

2.2 Common/Usual Name: Sonilase Light Device Red

2.3 Proprietary Names: Sonilase Light Device

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Codes: OHS

3. Device Description:

The Sonilase Light Deviceis a modular system that offers red light therapy for the treatment of wrinkles, rhytides, and fine lines in the periorbital region.

The Sonilase system components include the handheld unit containing the LED module , attachable clear plastic lens cover, an adjunct attachable cleansing brush head, recharging stand, 7.4V LI-ION BATTERY, 9V UL approved power supply , UV Sanitizing cradle and goggles.

The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components. The device is sold as Over the Counter (OTC).

4. Indications / Intended Use:

The Sonilase™ Light Device is used to treat periorbital wrinkles and fine lines around the eyes (i.e., crow's feet).

Rx or OTC:

> The Sonilase Light Device is an Over the Counter (OTC) device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate device is OTC.

5. Predicate Device:

This device is substantially equivalent to the following predicate device, which is currently in safe and effective commerce:

1. K110735 – Tanda Max OTC System (Pharos Life Corporation)

Predicate Chart

Device	**Tanda Max OTC System** **Pharos Life Corp.** **K110735** A Predicate Device	**Sonilase Red OTC System** **Biorenew Labs, LLC** **K132613** This Submission
Indications	The Tanda Max OTC System is intended to be used for the treatment of wrinkles, rhytides, and fine lines in the periorbital region.	The Sonilase Red OTC System is intended to be used for the treatment of wrinkles, rhytides, and fine lines in the periorbital region.
Handheld	Yes	Yes
Wavelength	660 nm	660 nm
Modes	On/Off	On/Off
Red power source	LEDs	LEDs

Device	Tanda Max OTC System Pharos Life Corp. K110735 A Predicate Device	Sonilase Red OTC System Biorenew Labs, LLC K132613 This Submission
Visible light LEDs	Yes	Yes
Energy Level	50 mW total	50 mW total
Power Supply	One 9v rechargeable alkaline battery	One 9v rechargeable alkaline battery
Treatment Time	160 seconds2 days per week for 6 weeks	160 seconds2 days per week for 6 weeks
Target Population	Individuals with periorbital lines and wrinkles.	Individuals with periorbital lines and wrinkles.
Location for Use	OTC	OTC

Summary of the technological characteristics of the device compared to predicate device:

1. Has the same intended use as the predicate (i.e., Treatment of wrinkles, rhytides and fine lines in the periorbital region;

2. Has the same output (i.e., 50 mW/cm2) as the predicate;

3. Utilizes the same wavelength (i.e., **660** nm) as the predicate device;

4. Utilizes the same treatment duration (i.e., **160** seconds) as the predicate device;

5. Utilizes the same treatment regimen of twice a week for six weeks.

The Sonilase Light Device and the above referenced predicate, Tanda Max OTC device, are Over the Counter Devices used to treat wrinkles as defined in 21 CFR § 878.4810. These devices utilize red diodes at 660nm to provide narrow bands of light energy to treat periorbital wrinkles. The performance achieved by these devices is similar with equal power output. The devices are handheld, and intended to be placed directly on the skin. They are manufactured out of similar materials. Based upon comparison to the predicate device, the Sonilase Light Device has the same intended uses, with similar

technological characteristics as the predicate device. The system performs as intended and does not raise any new safety or effectiveness issues.

6. Technological Characteristics

The Sonilase Light Device operates by a cordless system drawing upon its 7.4V rechargeable battery to deliver the treatment. The Sonilase Light Device delivery system used for applying therapy for the use in the treatment of periorbital wrinkles, is by emitting at least 50 mW/cm^2 of red (660nm) light via an electric light emitting diodes [LEDs] energy source. The device is not intended for ocular applications or direct eye exposure.

7. Performance Testing and Standards:

Testing of the Sonilase included functional performance testing, software validation testing and user safety testing.

The results of this testing are as follows:

Complies with IEC 60601-1-2 Electromagnetic Compatibility
Complies with IEC 60601-1-1 Electrical Safety

The Sonilase software was tested and validated in accordance with FDA's *"Guidance for the content of Premarket Submissions for Software Contained in Medical Devices"*

A Usability/Label Comprehension Study was conducted with 38 participants.
The results of the study found that:
100% of the participants were able to comprehend the labeling.
97% of the participants were able to use the device successfully.

9. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, and treatment regimes the manufacturer believes that no significant differences exist between the device and the predicate device. Therefore substantial equivalency is requested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biorenew Labs, LLC
% Ms. Susan Anthoney
AEGIS Regulatory Incorporated
2424 Dempster Drive
Coralville, Iowa 52241

February 5, 2014

Re: K132613
Trade/Device Name: Sonilase Light Device Red
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: January 5, 2013
Received: January 8, 2013

Dear Ms. Anthoney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132613

Device Name
Sonilase Light Device Red

Indications for Use *(Describe)*
The Sonilase™ Light Device Red is used to treat periorbital wrinkles and fine lines around the eyes (i.e., crow's feet).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
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FDA